5-6-81

TECHNICAL SUPPORT SECTION TOXICOLOGY REVIEW - I

Disinfectants Branch

IN 03/23-81 OUT 05/06/81

Reviewed by James E. Wilson, Jr. Date 05/04/81

EPA Reg. No. or File Symbol 5185-GGE (332)

EPA Petition or EUP No.

Date Division Received 03/02/81

Type Product(s): I, (D), H, F, N, R, S

Data Accession No(s). 244248

Product Mgr. No. 31 (Lee)

Product Name(s) Bio-Guard RTU

Company Name(s) Bio-Lab, Inc.

Submission Purpose New Product

Chemical & Formulation Liquid

Active Ingredient(s):	%
Alkyl (C_{12} 40%, C_{14} 50%, C_{16} 10%) dimethyl benzyl ammonium chloride	0.3%

1

D69105

300.0 Introduction

300.1 Uses

General use disinfectant cleaner.

300.2 Background

None

301.0 Data Summary

301.1 Brief Description of Studies

a. Acute Oral Toxicity in rats. Report by Consumer Product Testing Co., Inc., submitted to Bio-Lab, Inc., Decator, GA 30030, dated November 4, 1980. (Accession No. 244248).

b. Acute Dermal Toxicity in rabbits. Report by Consumer Product Testing Co., Inc., submitted to Bio-Lab, Inc., Decator, GA 30030, dated November 4, 1980. (Accession No. 244248).

c. Primary Dermal Irritation Study. Report by Consumer Product Testing Co., Inc., submitted to Bio-Lab, Inc., Decator, GA 30030, dated November 4, 1980. (Accession No. 244248).

d. Eye Irritation Study. Report by Consumer Product Testing Co., Inc., submitted to Bio-Lab, Inc., Decator, GA 30030, dated November 4, 1980. (Accession No. 244248).

301.2 Study Summaries

a. Acute Oral

1. Method

Ten albino rats, 5 male and 5 female, were given 5 g/kg of the test material orally. The animals were observed for signs of toxicity 1, 3, 6 and 24 hours after treatment and daily thereafter for 14 days. Body weights were taken on days 0, 7 and 14. All rats were subjected to necroprsy examinations and findings recorded.

2. Results

One female died on day 4. No other signs were recorded. The one rat which died had fibrous tissue encasing the heart and lungs along with fluid in the thoracic cavity. Body weight gains were in the normal range.

3. Conclusion

The oral LD_{50} of the product to rats is greater than 5.0 g/kg.

b. Acute Dermal

1. Method

Ten New Zealand white rabbits were clipped free of doral fur. The area was further prepared by abrading the area selected as the test site. Two grams per kg of the test material was placed on the test site and the area was covered and occluded for 24 hours. The animals were observed for signs of toxicity 1, 3, 6 and 24 hours after treatment and daily thereafter for 14 days. Body weights were recorded on days 0, 7 and 14. All animals were subjected to gross necropsy examinations.

2. Results

No mortality signs or pathology were reported. Body weight gains were normal.

3. Conclusion

The dermal LD_{50} of the product is greater than 2.0 g/kg.

c. Skin Irritation

1. Method

Six New Zealand white rabbits were clipped free of fur in the saddle area. Four test sites, two abraded and two intact, were identified. One-half ml of the test material was placed on each site and the area was covered and occluded for 24 hours. After the exposure period the coverings were removed and the reaction evaluated at 24 and 72 hours and 7 and 14 days after application.

2. Results

All rabbits showed some erythema after 24 hours. The irritation produced was generally slight. After 72 hours the average score for erythema was less than 1.0. Slight edema was observed in 4/6 after 24 hours. The number of animals showing this effect dropped to 3 at 72 hours and 0 after 7 days. Only one rabbit exhibited erythema after 7 days.

3. Conclusion

The chemical is a mild skin irritation.

d. Eye Irritation

1. Method

Nine adult albino rabbits were screened for eye defects with the aid of fluorescein stain. One-tenth of an ml of the chemical was placed in the conjunctival sac of one eye of each rabbit. The eyelids were held together for 1 second. Three of the eyes were flushed for 1 minute with lukewarm water 20-30 seconds after instillation. Reactions were observed 24, 48 and 72 hours and 4 and 7 days after instillation.

2. Results

Mild redness was found in 5/6 eyes after 24 hours and chemosis was observed in 1/6. No other reactions were recorded after the 24-hour reading.

3. Conclusion

The product is a very mild irritant to the eye.

302.0 Recommendations

302.1 Safety Supported by Data

The data submitted are adequate to establish the following toxicity categories:

Acute Oral	--	4
Acute Dermal	--	3
Eye Irritation	--	3
Dermal Irritation	--	4

302.2 Safety Not Supported by Data

None

302.3 Other Considerations

None

302.4 Additional Data Required

None

303.0 Labeling

Add the following statements to the precautionary section.

1. Causes eye injury.

2. Avoid contact with eyes.

3. Wash thoroughly with soap and water afer handling.

Delete the word "prolonged" from the precautionary section.

304.0 CRP Status

Product does not meet or exceed [redacted] criteria for CRP

4